

RFA 08-04: CIRM Bridges to Stem Cell Research Awards

I. Purpose

Rapid progress in stem cell research in California that will lead to the development of treatments and cures, and to the growth of the regenerative medicine and stem cell industry, will require an expanding pool of individuals with specialized training and skills. The CIRM Bridges to Stem Cell Research Awards will fund Research Internships and associated training activities for undergraduate and Master's level students. These CIRM-supported Research Internships will augment and be integrated with educational programs at the students' home institutions to provide comprehensive preparation and equip trainees for research and career opportunities in regenerative medicine.

II. Program Objectives

A major objective of the Bridges to Stem Cell Research Awards (Bridges Awards) is to augment the ranks of laboratory personnel trained in the state of the art techniques required by stem cell research labs. Personnel with knowledge and experience in cell culture techniques, microscopy, immunohistochemistry, fluorescence-activated cell sorting and analysis, micromanipulation techniques, cell transplantation and animal modeling techniques, and good laboratory practices (GLP) will play essential roles in advancing research from basic discoveries, through translational approaches, clinical investigations and commercialization. The Bridges Awards will both expand the pool of trained personnel and provide a mechanism to connect promising trainees with potential employers at stem cell laboratories in academia and industry.

A second goal of the Bridges Awards is to broaden the participation in stem cell research by individuals representing the diversity of California's population. In particular, the program will facilitate the involvement of students who do not otherwise have opportunities to take part in research focused on regenerative medicine. This initiative will provide a bridge between undergraduate and Master's level training in biotechnology or biomedical sciences and laboratories engaged in stem cell research.

RFA 08-04

Bridges to Stem Cell Research

7/22/2008

III. Program Features

Programs funded by the CIRM Bridges to Stem Cell Research Awards must be based at an applicant or "home" institution. The internships, which are a central feature of these programs, must take place in stem cell laboratories located at partner or "internship-host" institutions. All proposed training programs must include the following components:

A. Internships

Each program will feature CIRM-funded Research Internships in which trainees participate in stem cell related research projects in internship-host laboratories. Internship-host labs can be at California non-profit doctorate granting research universities, (as defined by the Carnegie Foundation for the Advancement of Teaching) or research institutes; or at California for-profit organizations. Internships cannot occur at the home institution. Internshiphost labs must be engaged in stem cell or related research and provide a research intensive environment.

CIRM will fund internships for a minimum of six months and a maximum of one year. Applicants should determine the optimal internship period for their particular program. Programs are permitted to have up to two types or tiers of internship (e.g. undergraduate-level internships and Master's level internships), and all internships within a tier must be of the same duration in each funded year. An individual student can be appointed to an internship for a maximum of one year.

Internship research is expected to be a full-time activity for which the trainee is compensated with a stipend and appropriate academic credit (determined by the home institution). Interns are expected to be enrolled as full-time students during the internship; the awards will fund tuition and educational fees during this period. CIRM will fund up to 10 internships per applicant per year. Applicants are encouraged to expand student participation and the size of their programs by involving additional trainees supported from other sources, if funding is available.

B. Educational Enhancement Activities

Programs will develop auxiliary educational activities to prepare students for internships and to augment the internship experience. Examples of such enhancements include seminar series, supplementary courses, and tissue culture training and specialized workshops. CIRM Bridges Awards will also support the development and delivery of a general education course (targeted to the general student population) in Stem Cells and Regenerative Medicine to be offered at the home institution.

C. Stem Cell Techniques Course

All trainees must participate in a stem cell laboratory techniques course given at a CIRM-funded Shared Research Laboratory or appropriate, equivalent facility in addition to their internship. Applicants should arrange for their students to enroll in an established course, or, in association with personnel from a Shared Research Laboratory, they may organize and coordinate a course specialized for their trainees.

D. Program Director

Each program will have a Program Director who leads and coordinates the CIRM Bridges Awards Program. This individual must be an experienced faculty member at the home institution. The Program Director will have primary responsibility for all programmatic and administrative aspects of the Bridges Award Program, including adherence to budgetary, policy, and reporting requirements.

E. Advisory Committee

Each program will have an Advisory Committee that establishes policies and guides ongoing planning and performance of the program. The Advisory Committee should include appropriate faculty from the home institution and must include at least one member who is a faculty member (or industry equivalent) from a partnering, internship-host institution.

F. Trainee Mentoring Plan

Programs must provide a Trainee Mentoring Plan that specifically describes how trainees will be advised and their progress assessed. Such a plan might include individual faculty sponsors at the home institution, individual mentoring committees with participation of the internship-host advisor, or other arrangements that provide for support and guidance of the trainees. The Trainee Mentoring Plan should also describe the frequency and nature of student assessment and plans for advising trainees on career and further educational opportunities.

IV. Award Information

A. Funds Available

Under this RFA, CIRM intends to commit up to \$18 million to support up to 10 awards. Each award will support up to 10 interns per year, and programs will be funded for up to three years. CIRM will provide each program with direct project costs of up to \$530,000 per year. Applicant home institutions may each apply for only one award.

B. Eligible Costs

Applicants may request program funding in accordance with the following categories and limits.

1. Trainee Expenses

- a. <u>Stipends</u> up to \$2500/month for each trainee engaged in full time research during an internship of up to one year duration.
- b. <u>Tuition and fees</u> up to \$5000 per year to the home institution for actual educational expenses for each trainee during the internship period.
- c. Research-related funds up to \$3000 per year for each trainee for costs to the internship-host laboratory.
- d. <u>Training course fees</u> up to \$2500 for each intern for fees and expenses (including travel) to a CIRM-funded Shared Research Laboratory or equivalent facility.

2. Program Administration and Educational Enhancement

Up to \$125,000 per year may be used for administrative support salaries, costs of developing or delivering new courses, seminar speakers, outside speakers for courses, audio-visual equipment or supplies, activities to enhance partnering between home and host institutions, or other activities that enhance the educational value of the program. Up to \$12,500 (of the \$125,000) may be used for salary support for the Program Director. Up to \$6,250 may be used for salary support of a faculty advisor or internship coordinator at internship-host institutions. Up to \$25,000 may be used to develop and deliver a general education course on Stem Cells and Regenerative Medicine. Justification for all Program Administration and Educational Enhancement expenses must be provided.

3. Indirect Costs

Indirect costs will be 10% of the total direct costs (Trainee Expenses and Program Administration and Educational Enhancement) less the costs for tuition and fees.

V. Eligibility Information

Applicant "home" institutions must be public universities or colleges, or non-profit academic institutions in California that are accredited by the Western Association of Schools and Colleges (WASC) and which do not have a CIRM-funded Shared Research Laboratory (i.e. were not recipients of an award from CIRM RFA 07-01). Non-profit means either: (1) a governmental entity of the State of California; or (2) a legal entity that is tax exempt under Internal Revenue Code section 501(c)(3) and California Revenue and Taxation Code section 23701d. Additionally, since the Bridges Awards must be associated with an appropriate comprehensive educational program, applicant institutions must have either 1) a Bachelor's or Master's degree program in Cell and Molecular Biology, Biotechnology, Biomedical Sciences or equivalent discipline, or 2) a Certificate or Associate degree program in Biotechnology or Biomedical Technology or equivalent.

Each eligible applicant institution may submit only a single application. Each Bridges Award will be granted to a single applicant home institution. The applicant institution may choose to collaborate with one or more additional institutions that would otherwise also be eligible to compete in order to provide broader program access to candidate trainees/interns. Collaborating institutions must meet the above institutional eligibility criteria and may not separately submit an application.

Applications must be submitted by a Program Director who is full-time faculty member at the applicant home institution.

VI. Review Criteria

Applications will be evaluated in three areas: the Training Program, Institutional Commitment and Partnering Arrangements, and Program Administration.

A. Training Program

1. Internships

- Appropriate and ample internship opportunities in stem cell labs will be readily available for trainees.
- Internship activities allow direct participation of trainees in stem cell and/or regenerative medicine research.
- Internships provide hands-on training in relevant laboratory techniques and approaches.
- Internships will have sufficient duration and oversight to achieve desired and stated educational objectives.

RFA 08-04

• The Trainee Mentoring Plan outlines beneficial and appropriate mechanisms to guide and support internship activities.

2. Educational Enhancement

- Educational enhancement activities support and complement internship experiences.
- Auxiliary activities will expand knowledge of stem cell science and regenerative medicine.
- The stem cell techniques course provides appropriate and beneficial training.

3. Educational Integration

- Internships, the requisite stem cell techniques course and educational enhancement activities are integrated effectively into a comprehensive degree or certificate program.
- Educational programs provide trainees with adequate and appropriate preparation for internships.

B. Institutional Commitment and Partnering Arrangements

1. Institutional Commitment

- Home institution is committed to the success of the training program.
- Home institution has a track-record of training in cell biology or biotechnology.
- Home institution and/or home department provides a supportive environment for preparing students for internships.

2. Partnering Arrangements

- Appropriate partnering (internship-host) institutions are identified and committed to participation in the training program and/or there is a well thought out plan in place for identifying such partners and evidence of progress in developing partnerships.
- Arrangements are established or planned for trainee enrollment in stem cell techniques course at CIRM-funded Shared Research Laboratory or appropriate equivalent facility.

C. Program Administration

- Program Director has appropriate experience in education and administration.
- Composition and duties of program Advisory Committee are well defined and beneficial to the program.

- Mechanisms are established for recruitment of qualified and diverse program participants.
- Procedures for tracking of trainee accomplishment are developed.

VII. Application Procedure

Applicant institutions must follow these instructions for submitting a Letter of Intent and Application for the Bridges to Stem Cell Research Awards. Applications will only be accepted from institutions that have submitted a Letter of Intent (LOI) that is accepted by CIRM.

A. Letter of Intent

All institutions planning to apply for a CIRM Bridges Award must submit a Letter of Intent (LOI) using the LOI template provided at http://www.cirm.ca.gov/grants/default.asp. The letter should describe concisely an overview of the proposed Bridges program. Letters of intent are non-binding, but applications will not be accepted from institutions that have not had such a letter accepted by CIRM. Letters of intent must be sent as an email to BridgesAwardLOI@cirm.ca.gov and must arrive by 5:00 PM (PDT), July 31, 2008. No exceptions will be made.

B. Application Instructions

Application forms will be available on the CIRM website http://www.cirm.ca.gov/grants/default.asp. The application for a CIRM Bridges to Stem Cell Research Award consists of five parts:

Part A: Application Information Form (Adobe PDF template provided at http://www.cirm.ca.gov/grants/default.asp). Part A includes: Abstract, Public Abstract, and Statement of Benefit to California, Key Personnel, and Budget (section numbers 1, 2, 3, 4, 5, 6, and 7)

Part B: Bridges Award Program Proposal (MS Word template provided at http://www.cirm.ca.gov/grants/default.asp). Part B includes: Overall Program Design, Trainee Selection and Placement, Mentoring and Trainee Assessment, and Program Leadership and Administration (section numbers 8, 9, 10, and 11).

Part C: Internship Host Lab Summary (Adobe PDF template provided at http://www.cirm.ca.gov/grants/default.asp). (section number 12).

Part D: Biographical Sketches for Key Personnel and Advisory Committee Members (MS Word templates provided at http://www.cirm.ca.gov/grants/default.asp).

Part E: Institutional Letter of Commitment and other letters of commitment or agreement (No template provided; section number 10).

The applications for CIRM Bridges to Stem Cell Research Awards include the following sections:

- Abstract (up to 3000 characters in Part A)
 Describe the proposed program of training including the level of training, the numbers of trainees, the nature of the educational program with which the internships will be integrated, nature and scope of courses and ancillary activities, and the range of research opportunities available to interns in the program.
- 2. Public Abstract (up to 3000 characters in Part A)
 Briefly describe the proposed training program and how it will directly
 or indirectly contribute to the training of laboratory personnel and
 bolster stem cell research. This Public Abstract will become public
 information; therefore, do not include confidential information or
 information that could identify the applicant institution.
- 3. Statement of Benefit to California (up to 1500 characters in Part A)

 Describe in a few sentences how the proposed program will benefit the state of California and its citizens. This Statement of Benefit will become public information; therefore, do not include proprietary or confidential information or information that could identify the applicant institution.
- 4. Key Personnel (included in Part A)
 List the Program Director and key administrative personnel. A
 minimum of one percent effort is required for each key person. Do not
 include internship-host mentors, Advisory Committee members, or
 internship host coordinators in this section. For Program Director
 provide a 2 page biographical sketch using the template provided
 (included in Part D). The biosketch should highlight prior experience
 and/or special skills related to the proposed program.
- 5. Internship-host and Techniques Course-host Institutions (included in Part A)
 List Internship-host and Techniques Course-host institutions with which agreements or arrangements for trainee placement and training have been established. Programs may partner with up to 4 nonprofit institutions and with an unlimited number of for-profit organizations. Identify a contact individual for each internship-host and techniques course-host institution and indicate in what role they

will serve (e.g. Internship-host Faculty Advisor/Internship Coordinator, Course Director, etc.).

6. Advisory Committee Members (included in Part A)
List each member of the Advisory Committee for the proposed
program. The Advisory Committee must contain at least one member
who is a faculty member (or industry equivalent) from a partnering,
internship-host institution. For each individual listed, provide a
biographical sketch in Part D.

7. Budget (included in Part A)

Provide all budget information requested in the budget section of the application form. Allowable costs under this RFA are described above (Section IV.B.).

- 8. Overall Program Design (up to 4 pages in Part B)
 - a. Describe the specific focus and purpose of the training program including the level(s) of proposed trainees.
 - b. Describe the training to be offered as part of the program including:
 - i. internship duration and scope
 - ii. required courses (describe briefly the material to be covered in each course)
 - iii. auxiliary training activities
 - iv. Stem Cell techniques course at a CIRM-funded Shared Research Laboratory or appropriate equivalent facility (include a brief description of planned course content and arrangements that are planned or in place for coordinating this activity)
 - c. Describe how the internships and other proposed training activities will be integrated into a comprehensive educational program.
 - d. Describe any plans to collaborate with other institutions that will supply trainees participating in the program; include a letter of agreement from each collaborating institution describing the nature of the collaboration.
- 9. Trainee Selection and Placement (up to 2 pages)
 - a. Describe how trainees will be recruited to the program and selected for participation.
 - b. Summarize the internship opportunities available to trainees. If specific internship host mentors have committed to participation in the program, supply information about these individuals in Part C of the application. If specific opportunities are not yet in place, summarize plans for and status of establishing internship opportunities. Include any letters or agreements from candidate internship-host institutions indicative of their commitment to or interest in participation as a host institution.

- c. Describe the process by which trainees will be placed in internships.
- 10. Mentoring and Trainee Assessment (up to 1 page in Part B)
 - a. Provide the Trainee Mentoring Plan that describes how trainees will be mentored.
 - b. Describe how trainee progress and accomplishment will be assessed.
- 11. Program Leadership and Administration (up to 1 page in Part B)
 - a. Describe plans for the educational and administrative leadership and oversight of the program.
 - b. Describe the composition, duties, and meeting frequency of the program Advisory Committee. Include in section C biosketches for all committee members.
- 12. Internship-host Lab Summary (included in Part C)
 List prospective internship host mentors. List only those individuals
 who have agreed to accept trainees for internships and are
 committed to participate in the proposed program. Note: applicants
 are not required to complete this section; complete this form only for
 specific internship opportunities that are in place at time of application.
- 13. Institutional Commitment (up to 2 pages in Part E)
 - The applicant institution must provide a letter of support, signed by a senior organizational official who has the authority, or who has been delegated the authority, to commit the applicant institution to support the proposed program. This letter should document in specific terms the nature of the institution's current and future commitment to the proposed program during the period of the award and should include a description of facilities and resources available to the program. A discussion of the institution's track record and future plans for expanding educational activities relevant to the proposed program should also be included.

VIII. SUBMITTING AN APPLICATION

Applications will only be accepted from institutions which have submitted a Letter of Intent (LOI) that was accepted by CIRM.

The application for CIRM Bridges to Stem Cell Research Awards consists of <u>five</u> parts:

Part A: Application Information Form (Adobe PDF template provided at http://www.cirm.ca.gov/grants/default.asp).

Part B: Bridges Awards Program Proposal (MS Word template provided at http://www.cirm.ca.gov/grants/default.asp).

Part C: Internship Host Lab Summary (Adobe PDF template provided at http://www.cirm.ca.gov/grants/default.asp).

Part D: Biographical Sketches for Key Personnel and Advisory Committee members (MS Word templates provided at http://www.cirm.ca.gov/grants/default.asp).

Part E: Institutional Letter of Commitment (no template provided)

All five parts of the application for CIRM Bridges to Stem Cell Research Awards must be submitted together in both hard copy and electronic formats and received by CIRM no later than 5:00 PM (PDT), September 16, 2008. This is the applicant's responsibility and no exceptions will be made. Applicants must use the appropriate CIRM templates to complete Parts A, B, C, and D.

Send electronic copies of all five parts of the application as attachments in a single email to BridgesAwards@cirm.ca.gov. In addition to the electronic submittal, candidates must submit an original copy of the application signed by both the Program Director and the institution's Authorized Organizational Official, plus 5 paper copies (preferably double-sided) of the application to:

Bridges Awards Application California Institute for Regenerative Medicine 210 King Street San Francisco, CA 94107

The original application plus the five copies must be received by CIRM no later than 5:00 PM (PDT), September 16, 2008. This is the applicant's responsibility and no exceptions will be made.

IX. SCHEDULE OF RECEIPT AND ANTICIPATED REVIEW

Receipt of Letters of Intent:	5:00 PM (PDT), July 31, 2008
Receipt of Applications:	5:00 PM (PDT), September 16, 2008
Review of Applications by Grants Working Group (GWG):	November, 2008
Review and Approval by ICOC:	Early 2009
Earliest Funding of Awards:	Spring, 2009

X. REVIEW AND AWARD PROCESS

CIRM Bridges to Stem Cell Research applications will be reviewed by the CIRM Scientific and Medical Research Funding Working Group (the Grants Working Group, or GWG). The GWG consists of fifteen basic and clinical scientists from institutions outside California, seven patient advocates who are members of the Independent Citizen's Oversight Committee (ICOC), and the Chair of the ICOC. The membership of the GWG can be viewed at http://www.cirm.ca.gov/workgroups/pdf/GrtWkgGpMbr.pdf. The ICOC was established by the California Stem Cell Research and Cures Act (Proposition 71) to oversee CIRM and makes all final funding decisions. The composition of the ICOC can be viewed at http://www.cirm.ca.gov/fag/pdf/Members.pdf. Fifteen scientists on the GWG together with select specialists with expertise in undergraduate and Master's level educational programs will review the applications and rate them according to educational, organizational, and technical merit. For Bridges to Stem Cell Research Awards applications, particular emphasis will be placed on the training program, the institutional commitment and partnering arrangements, and the program administration.

The GWG's final recommendations for funding will then be forwarded to the ICOC, which will make all final funding decisions.

XI. CONTACTS:

For information about this RFA: Michael P. Yaffe, Ph.D. Scientific Officer California Institute for Regenerative Medicine 210 King Street San Francisco, CA 94107 Email: myaffe@cirm.ca.gov

Tel: 415-396-9238

Fax: 415-396-9141

For information about the review process:

Gilberto R Sambrano, Ph.D.

Senior Officer to the Grants Working Group

California Institute for Regenerative Medicine

210 King Street

San Francisco, CA 94107

Email: gsambrano@cirm.ca.gov

Phone: (415) 396-9103 FAX: (415) 396-9141

For information about electronic forms:

Ed Dorrington

Director of Grants Management Systems

California Institute for Regenerative Medicine

210 King Street

San Francisco, CA 94107

Email: edorrington@cirm.ca.gov

Phone: (415) 396-9108 FAX: (415) 396-9141

For programmatic information:

Patricia Olson, Ph.D.

Director of Scientific Activities

California Institute for Regenerative Medicine

210 King Street

San Francisco, CA 94107 Email: polson@cirm.ca.gov Phone: (415) 396-9116

FAX: (415) 396-9141

XII. OTHER REQUIREMENTS

A. CIRM Grants Administration Policy:

CIRM's Grants Administration Policy (GAP) for Academic and Non-profit Institutions serves as the standard terms and conditions of grant awards issued by CIRM except as noted herein. All research conducted under this award must comply with the stated policy, which can be found on the CIRM website at: http://www.cirm.ca.gov/reg/pdf/reg100500 policy.pdf. Funding from year to year will depend on progress achieved.

B. Evaluation of the Program:

In fulfilling our commitment to the State of California, CIRM may request information essential to an assessment of the effectiveness of this program. Accordingly, recipients are hereby notified that they may be contacted after the

completion of this award for periodic updates on various aspects of compliance with CIRM regulations and grant conditions, including; employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program. CIRM also retains the right to audit all expenditures of CIRM funds.

C. Human Stem Cell Research Regulations:

CIRM has adopted medical and ethical standards for human stem cell research. All research conducted under this award will be expected to comply with these standards which can be viewed at:

http://www.cirm.ca.gov/reg/pdf/AdoptedRegs 100010.pdf. While these regulations prohibit donors of gametes, embryos, somatic cells or human tissue from receiving valuable consideration for their donation, they do allow for reimbursement for permissible expenses as determined by an IRB. "Permissible Expenses" means necessary and reasonable costs directly incurred as a result of donation participation in research activities and may include costs such as those associated with travel, housing, child care, medical care, health insurance and actual lost wages. For research activities proposing to obtain gametes, embryos, somatic cell or human tissue from human subjects, CIRM requires the candidate to submit, at the time of application, their reimbursement policy describing how they intend to calculate permissible expenses.

D. Intellectual Property Policy for Non-profit Organizations:

CIRM has adopted policies that govern intellectual property resulting from CIRM-funded research that also govern this award. This policy can be viewed at: http://www.cirm.ca.gov/reg/pdf/IP Regs 100300.pdf